

### **REMARKS**

#### **Amendment After Final Rejection**

The undersigned thanks the Examiner for entering the Amendment After Final filed on July 9, 2003. That amendment was responsive to the Examiner's statements on page 4 of the office action concerning blanks in the specification.

#### **Rejection of Claims 61-88 Under 35 U.S.C. §§ 101 and 112, First Paragraph**

Claims 61-88 are rejected under 35 U.S.C. § 101 as lacking specific and substantial asserted utility or well established utility, and under 35 U.S.C. § 112, first paragraph, as not being enabled.

The Examiner states throughout the record that applicants have not disclosed a specific and substantial utility for CRSP-2. For example, the Examiner states that the specification discloses "only vague generalities concerning the fact that CRSP proteins are secreted proteins and ascribes utility ... based upon their inclusion in the broad family of secreted proteins," and "[t]he activities enumerated as 1-6 on page 11 are written in such broad terms, they merely encompass several functions known to be performed by proteins in general." (Office Action dated April 9, 2003, at page 4; Office Action dated November 6, 2000, at page 3.) The Examiner further states, "there is no concrete statement of what any CRSP protein does," and questions whether it "catalyze[s] a reaction," "bind[s] DNA," or "bind[s] protein?" (Office Action dated November 6, 2000, at page 3.)

It is an axiom of patent law that "it is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works." In re Cortright, 49 USPQ2d 1464, 1469 (Fed. Cir. 1999) (quoting Newman v. Quigg, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989)). However, the Examiner's statements demonstrate that the criteria for evaluating whether an asserted utility is specific and substantial are being applied to this application in a manner contrary to binding case law and to the PTO Utility Examination Guidelines ("Guidelines," MPEP § 2107, 8<sup>th</sup> ed., Rev.1 (Feb. 2003)). In particular, the Examiner appears to be looking for an assertion of utility that has a degree of particularity that amounts to disclosure of how or why the invention works, *e.g.*, the molecular interactions or molecular mechanisms underlying the utility of CRSP-2. This approach is inconsistent with the case law and with the Guidelines.

### Specific Utility

In the application, Applicants assert that CRSP-2 and other CRSP proteins, have utility in modulating cellular signal transduction, particularly in cells involved in development and differentiation. Applicants make this assertion by discussing, in the introduction, the role of secreted proteins in cellular signaling during the formation, differentiation and maintenance of cells and tissues. (Specification at page 1.) Applicants also teach that CRSP-2 and other CRSP proteins have at least one of the following activities:

(1) modulation of cellular signal transduction, either *in vitro* or *in vivo*; (2) regulation of gene transcription in a cell involved in development or differentiation, either *in vitro* or *in vivo*; (3) regulation of gene transcription in a cell involved in in [sic] development or differentiation, wherein at least one gene encodes a differentiation-specific protein; (4) regulation of gene transcription in a cell involved in in [sic] development or differentiation, wherein at least one gene encodes a second secreted protein; (5) regulation of gene transcription in a cell involved in development or differentiation, where at least one gene encodes a signal transduction molecule; and (6) regulation of cellular proliferation, either *in vitro* or *in vivo*.

(Specification at page 11, lines 23-32.)

The application asserts and discloses utilities for the claimed polypeptides that are specific utilities as defined in the Guidelines. According to the Guidelines, a specific utility is specific to the claimed subject matter, whereas a general utility is applicable to the broad class of the claimed subject matter. (MPEP § 2107, at 2100-32.) The Guidelines point out that applications that disclose a specific use or application of an invention (a specific utility) are to be distinguished from applications that state that an invention is useful without identifying with specificity why it is useful (a general utility). (*Id.*) The Guidelines also state that a specific utility is not asserted when the application merely discloses that a compound has “useful biological” properties. (*Id.*)

Applicants’ asserted and disclosed utilities are specific utilities because they disclose the utility of CRSP-2 and other CRSP proteins, with specificity (*e.g.*, modulating cellular signal transduction, particularly in cells involved in development and differentiation) and with varying degrees of particularity. The application does not disclose particular molecular interactions or mechanisms through which CRSP-2 proteins function. However, this level of detail is not

required by the patent statutes, and inventors are not required to disclose or even know how or why the invention works. Cortright, 49 USPQ2d at 1469. Moreover, the Guidelines demonstrate that these assertions are of a specific utility. For example, in the section of the specification quoted above, Applicants disclose that CRSP-2 and other CRSP proteins, have at least one of six enumerated specific biological properties, such as modulating cellular signal transduction and regulating gene transcription in a cell involved in development or differentiation. Each of the enumerated properties relates to a specific art-known biological process. Therefore, the enumerated properties are assertions of a specific utility and are readily distinguished from the general assertion that a claimed composition has “‘useful biological’ properties,” referred to in the Guidelines. (MPEP § 2107, at 2100-32.)

The burden is on the Patent Office to establish that the asserted utilities are not specific utilities. The Examiner states in the record that these asserted utilities “merely encompass several functions known to be performed by proteins in general.” (Office Action dated November 6, 2000, at page 3.) However, the Examiner has not presented any evidence or scientific reasoning showing that proteins in general or even secreted proteins in general have these asserted utilities. Under the circumstances the burden has not been met.

#### Substantial Utility

The asserted utilities are substantial utilities. The U.S. Supreme Court has held that substantial utility exists “where specific benefit exists in currently available form,” (Brenner v. Manson, 383 U.S. 519, 534-35 (1966)), and according to the Guidelines, a substantial utility defines a real world use. (MPEP § 2107, at 2100-32.) According to the Guidelines, a utility that requires further research to identify or reasonably confirm a real world context of use is not a substantial utility. (MPEP § 2107, at 2100-32.)

The utilities asserted by Applicants define real world uses. For example, Applicants assert that CRSP-2 is useful in modulating cellular signal transduction, particularly in cells involved in development and differentiation, and have at least one of six specific biological properties enumerated on page 11 of the specification. (*Supra.*) These are real world utilities that provided a specific benefit at the time the application was filed. For example, in certain contexts of use that are readily apparent from the teachings of the specification, such as *in vitro* systems, the claimed polypeptides provide a means for studying and elucidating the mechanisms

and processes that underlie development and or differentiation of cells and tissues. This benefit is provided by the application as filed. This type of use and the benefit it provides is distinct from use of CRSP-2 for further study of CRSP-2 itself. For example, in certain contexts of use, such as *in vitro* systems, the claimed polypeptides can be viewed as “research tools” for regulating cellular proliferation. (See, MPEP § 2107, at 2100-33.) This type of use provides the specific benefit of creating an opportunity to analyze cells that are in a desired proliferative state. Such a use of the claimed polypeptides unquestionably defines a specific and substantial utility, because further research is not required to identify or confirm this use, and it provides the specific benefit of being able to analyze the physiological characteristics of cells in a desired proliferative state. Moreover, Applicants have provided evidence that CRSP proteins, including CRSP-2, have specific and substantial utility that is supported by the specification. In particular, Krupnick *et al.* (Reference DQ of record) and Mao *et al.* (previously discussed in the Amendment After Final, and cited in the Supplemental Information Disclosure Statement filed concurrently) confirm that CRSP-2 and other CRSP proteins have specific and substantial utility as disclosed in the specification.

The Examiner does not appear to question the credibility of the asserted utility. However, even if the credibility of the asserted utilities were questioned, Krupnick *et al.* and Mao *et al.* demonstrate that CRSP-2 and other CRSP proteins, do in fact have utility as disclosed in the specification. Because, the Applicants’ asserted utility is supported by evidence, it must be considered credible.

The application as filed discloses that the claimed polypeptides have utility in modulating cellular signal transduction, particularly in cells involved in development and differentiation and have at least one of the specific biological properties listed in the specification. The claimed polypeptides have a specific and substantial utility because proteins in general are not useful for modulating cellular signal transduction, no further experimentations is needed to confirm the asserted utility, and the claimed polypeptides provide a real world benefit. A detailed disclosure of how or why the claimed polypeptides work is not required to satisfy the utility requirement or any other requirement of the patent statutes. Cortright, 49 USPQ2d at 1469.

The rejection under 35 U.S.C. § 112 is based solely on the Examiner’s opinion that the application does not satisfy the utility requirement. No reasoning or evidence tending to show

that the person of skill in the art would not be able to make or use the claimed polypeptides without resorting to undue experimentation has been made of record.

For the reasons discussed above, and in accordance with the standards set forth in the case law and the Guidelines, the application discloses a specific, substantial and credible utility for the claimed polypeptides. Withdrawal of the rejections under 35 U.S.C. §§ 101 and 112, first paragraph is requested.

Information Disclosure Statement

A Supplemental Information Disclosure Statement (SIDS) is being filed concurrently herewith. Acknowledgment of consideration of the information provided therein is requested in the next Office Communication.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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